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## Predictors of Outcome in Patients With (Sub)Acute Low Back Pain Differ Across Treatment Groups

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**Study Design.** Prospective study with 6 weeks of follow-up.

**Objective.** To examine the predictors of outcome for patients with (sub)acute low back pain (LBP) receiving usual care (UC) or a minimal intervention strategy (MIS) aimed at psychosocial factors.

**Summary of Background Data.** A randomized controlled trial in general practice showed no differences in average effect between UC and MIS.

**Methods.** Socio-demographic variables, characteristics of LBP, and psychosocial factors were included as potential predictors of outcome. The outcome clinically important improvement was defined as a reduction of at least 30% on functional disability plus patient perceived recovery. Logistic regression analyses were used to study the associations between predictors and outcome at 6 weeks follow-up.

**Results.** In the UC group ( $n = 163$ ), the multivariable model included a shorter duration of the LBP episode, few previous episodes, less pain catastrophizing, and good perceived general health. The area under the curve (AUC) of the model was 0.77 (95% confidence interval, 0.70–0.85). In the MIS group ( $n = 142$ ), the multivariable model included less somatizing symptoms, more solicitous responses by an important other, lower perceived risk for chronic LBP, more fear avoidance beliefs, higher level of education, and shorter duration of the LBP episode. This AUC was 0.78 (95% confidence interval, 0.71–0.86).

**Conclusions.** As we found two different profiles, our approach may contribute to the important question: what intervention works for whom?

**Key words:** back pain, prognosis, patient characteristics, usual care, minimal intervention strategy, general practice. *Spine* 2006;31:1699–1705

convincingly demonstrated.<sup>1</sup> One way to improve treatment effectiveness may be to match treatments (better) to patient characteristics.<sup>2,3</sup> Vlaeyen and Morley<sup>3</sup> discuss several approaches to answering the question: what works for whom? One of the approaches may be delivering treatments only to patients who perceive these treatments as being highly credible because perceived credibility appears to be one of the stronger predictors of outcome.<sup>4</sup> Another approach may be tailoring treatment to the patient's readiness to change as described by the stages of change model.<sup>5</sup> According to this model, patients vary in the extent to which they are willing to adopt a self-management approach to their problem. Developing and validating prediction rules to identify those who respond favorably to a specific intervention may constitute a third approach.<sup>6,7</sup>

Inspired by these approaches, we decided to reanalyze the data from our cluster-randomized clinical trial from a different perspective. The main results revealed no relevant or statistically significant mean effects between usual care (UC) and a minimal intervention strategy (MIS) aimed at psychosocial factors for patients with (sub)acute LBP in general practice.<sup>8</sup> Our study groups were similar at baseline, the sample size was sufficient ( $n = 314$ ), dropout rate was low (9%), and we used multilevel analysis to adjust for possible effects of clustering within practices. Therefore, we concluded that it was unlikely that methodologic flaws explained the lack of difference in mean effect between MIS and UC in our trial.<sup>8</sup>

In the present paper, we explored the hypothesis that the characteristics of patients showing a favorable outcome may have been different in the UC and MIS groups, even though the proportions of patients showing a favorable outcome were similar in both groups. Therefore, we determined per treatment group which combination of factors predicted a favorable outcome at 6 weeks of follow-up.

### ■ Materials and Methods

**Design.** We conducted a prospective study among participants of a cluster-randomized controlled trial.<sup>8</sup> In this trial, randomization took place at the level of the general practice: 21 practices (32 GPs) were randomized to the UC group and 20 practices (28 GPs) to the MIS group.

**Recruitment.** Patients were recruited by their GP. GPs were asked to select the first 10 patients who consulted them for LBP and who met the following criteria: age 18 to 65 years, non-specific LBP as main complaint, duration of LBP less than 12

Although a large variety of therapeutic interventions is available for the treatment of low back pain (LBP), the effectiveness of most of these interventions has not been

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weeks or an exacerbation of mild symptoms, and sufficient knowledge of the Dutch language. Exclusion criteria were: LBP caused by specific pathologic conditions (metastasis, osteoporosis, rheumatoid arthritis, or fracture), LBP currently treated by another healthcare professional, and pregnancy. The study was approved by the Medical Ethics Committee of the VU University medical center, Amsterdam, The Netherlands.

**Management of Low Back Pain.** The GPs in the UC group provided care as usual, which was not standardized with respect to content and number of consultations. We assumed that the GPs would adhere to the clinical guideline for LBP of the Dutch College of General Practitioners.<sup>9</sup> For acute LBP, this guideline advises a wait-and-see policy with pain medication and gradual increase in activities, and provides general recommendations regarding return to activity and home exercises. For subacute LBP (>6 weeks), the clinical guideline advises referral for physical therapy in case of persistent functional disability. The guideline lacks explicit guidance on psychosocial factors.

The GPs in the MIS group aimed their treatment at identification and discussion of psychosocial prognostic factors, such as the patient's own ideas on the cause of their LBP, fear avoidance beliefs, worries regarding the pain, pain catastrophizing, pain behavior, and reactions from the social environment (family, friends, work) regarding LBP. This consultation took about 20 minutes and is described in detail elsewhere.<sup>8</sup>

**Definition of Outcome.** Clinically important improvement after 6 weeks was defined as an improvement in functional disability of at least 30% plus a perceived recovery rating of at least much improved.<sup>10</sup> Functional disability was assessed by the 24-item Roland-Morris Disability Questionnaire (RDQ; 0–24).<sup>11</sup> Perceived recovery was scored by the patient on a 7-point Likert scale (very much/much/slightly improved, no change, slightly/much/very much worse).<sup>12</sup> Data about functional disability and perceived recovery were collected using postal questionnaires.

**Potential Predictors.** Patients' baseline data were collected during a home visit by a research assistant. The baseline questionnaire contained several questions on socio-demographic variables (*i.e.*, age, education level, insurance), characteristics of LBP, psychosocial factors, and judgments made by GP or patient.

The following characteristics of LBP were measured: pain intensity (0–10)<sup>13</sup>; radiation (yes/no); radiation below knee (yes/no); duration and frequency of LBP complaints; other pain sites (yes/no); and severity of the main complaint (0–10).<sup>14</sup> We included the following psychosocial factors: fear avoidance beliefs, using the 4-item physical activity subscale of the Fear Avoidance Beliefs Questionnaire (FABQ, 0–24)<sup>15</sup>; pain catastrophizing, using the 6-item subscale of the Coping Strategies Questionnaire (CSQ, 0–36)<sup>16</sup>; distress and somatization, measured by the 16-item subscales of the 4 Dimensional Symptom Questionnaire (4DSQ, 0–32)<sup>17</sup>; perception of one's own potential to influence health, scored by the patient on a 4-point Likert scale (no influence, hardly any, reasonable, much influence)<sup>18</sup>; perceived general health, using the first question of the subscale "general health perceptions" of the Short Form Health Survey (SF-36, 1–5)<sup>19</sup>; and, lastly, punishing, solicitous and distracting responses of a significant other to the pain (as perceived by the patient), assessed by part two of the Multidimensional Pain

Inventory (MPI, 0–6).<sup>20</sup> Both patients and GPs judged the risk the patient would develop chronic LBP (0–10), while GPs in the MIS group also predicted the effectiveness of the MIS (0–10) for each patient.

**Statistical Analysis.** All analyses were performed separately for UC and for MIS. Continuous variables were examined to check whether there was a linear relation between the potential predictor and the outcome. Potential predictors showing a non-linear relation with outcome were in principle divided into three categories. However, when this was not possible, or when a cutoff score was available from literature, potential predictors were dichotomized. Next, univariable logistic regression analyses were performed for all potential predictors with the outcome measure. We present the univariable odds ratios (ORs) along with the 95% confidence intervals (95% CI). When a potential predictor showed a linear relation with outcome in one intervention group and a nonlinear in the other, both an OR per point and an OR per category are presented. Variables that were associated with the outcome ( $P < 0.20$ ) were selected for the multivariable analysis. Before multivariable analysis was applied, the correlation among predictors was checked. In case of a high correlation (Spearman  $r > 0.5$ ) between two variables, the predictor with the strongest univariable association with outcome was retained in the multivariable regression model. All predictors were entered simultaneously in a multivariable logistic regression model. The best predictive model was constructed using a manual backward selection method. Variables with the lowest predictive value were deleted from the model until further elimination of a variable resulted in a statistically significant lower model fit as estimated with the log likelihood ratio test ( $P < 0.10$ ).

**Evaluation of the Model.** The discriminative ability of the model was assessed by the area under the receiver-operating characteristic curve (ROC) plus 95% CI. The ROC-curve plots the true positive rate (sensitivity) against the false-positive rate ( $1 - \text{specificity}$ ) at any given cutoff value. The curve illustrates the ability of the model to discriminate between patients with and without a favorable outcome at subsequent cutoff values. An area under the curve (AUC) of 0.5 indicates no discrimination above chance, whereas an AUC of 1.0 indicates perfect discrimination. The reliability of the multivariable model was determined by using the Hosmer-Lemeshow goodness-of-fit statistic.<sup>21</sup> A  $P < 0.10$  indicates inadequate fit of the model.

## ■ Results

### Study Population and Baseline Characteristics

Between September 2001 and April 2003, 314 patients were enrolled in our study: 171 in the UC group and 143 in the MIS group. Table 1 shows that baseline characteristics were largely similar for the two treatment groups.

### Outcome

Data about recovery after 6 weeks were missing for 8 persons in the UC group (5%) and for 1 person in the MIS group (1%). After 6 weeks, 52.7% (86 of 163) of the patients in the UC group and 47.9% (68 of 142) in the MIS group showed clinically important improvement according to our definition.

The mean  $\pm$  SD scores for functional disability (RDQ) and pain intensity were lower for patients defined as

**Table 1. Baseline Characteristics of Patients With (Sub)Acute Low Back Pain**

		UC (n = 171)	MIS (n = 143)
<b>Demographic characteristics</b>			
Age	Mean (SD)	42.0 (12.0)	43.4 (11.1)
Gender	% female	47.4	47.6
Nationality	% Dutch	97.7	97.2
Health insurance	% public	67.8	70.6
<b>Educational level and work status</b>			
Educational level*	%		
≤primary		33.1	35.0
Secondary		52.7	46.2
College, university		14.2	18.8
Paid job	% yes	81.3	81.8
Sick leave because of LBP (among the working population)*	% yes	41.0	34.8
<b>Characteristics of LBP</b>			
Duration current episode (days)	Median (IQR)	14 (7–21)	11 (5–21)
Frequency of LBP episodes last year	%		
1 or 2 episodes		60.8	58.0
3 or more episodes		18.7	19.6
Exacerbation of persisting LBP		20.5	22.4
Pain intensity during the day (0–10)†	Mean (SD)	4.8 (2.0)	4.9 (2.0)
Pain radiating below knee*	% yes	14.6	12.6

UC = usual care; MIS = minimal intervention strategy; SD = standard deviation; LBP = low back pain; IQR = interquartile range (25th–75th percentile).

\*Data of 2 patients are missing.

†Data of 1 patient is missing.

improved (RDQ,  $2.5 \pm 3.1$ ; pain,  $0.8 \pm 1.4$ ) than for those defined as not improved (RDQ,  $8.7 \pm 5.2$ ; pain,  $3.7 \pm 2.6$ ). No differences on these scores were found between UC and MIS.

### Predictors of Outcome

Table 2 presents per intervention group the univariable association of potential predictors with outcome after 6 weeks. The variables included in the prediction models after backward stepwise selection are presented in Table 3. Despite an univariable association with outcome of  $P < 0.20$ , self-perceived risk to develop chronic LBP was not entered in the multivariable model of the UC group because of strong correlations with pain catastrophizing (Pearson  $r = 0.52$ ). In the UC group, a higher probability of a favorable outcome was associated with a combination of a shorter duration of the current LBP episode, a history of 2 or less episodes of LBP in the previous year (including the present episode), less pain catastrophizing, and a better perceived general health. The AUC for the model was 0.77 (95% CI, 0.70–0.85), while the Hosmer and Lemeshow test showed adequate goodness of fit ( $P > 0.10$ ).

In the MIS group, a higher probability of a favorable outcome was associated with a combination of a shorter duration of the current LBP episode, less somatization, more solicitous responses by an important other, a lower susceptibility (estimated by the patient) to develop chronic LBP, more fear avoidance beliefs, and a higher level of education. The AUC for the model was 0.78 (95% CI, 0.71–0.86), while the Hosmer and Lemeshow test showed adequate goodness of fit ( $P > 0.10$ ).

### Discussion

The present study showed that almost all predictors of favorable outcome after 6 weeks differed across UC and

MIS. Clearly, the profile of patients responding favorably to UC differed from those responding favorably to MIS. This finding is intriguing as the baseline characteristics and the mean changes in outcome measures did not differ across both groups.<sup>8</sup>

### Predictors of Outcome in the UC Group

UC seemed to be especially effective in patients with a short duration of the current LBP episode, few episodes of LBP in the last year, less pain catastrophizing, and who perceive their general health as good. Or, somewhat overstated, UC seems effective in “uncomplicated cases of LBP.” Although we could not find evidence in the literature for this combination of predictors, each of these has been identified before as predictor of chronic LBP (previous LBP episodes<sup>22</sup>; perceived general health<sup>22,23</sup>; pain catastrophizing<sup>22–24</sup>; duration of LBP<sup>25</sup>).

### Predictors of Outcome in the MIS Group

MIS seemed to be especially effective in patients with a high level of education, a short duration of the current LBP episode, few somatizing symptoms, many solicitous responses by an important other, a low risk to develop chronic LBP according to the patient, and more fear avoidance beliefs. Or, somewhat overstated, MIS seemed to be beneficial in highly educated patients with a solicitous system of support, who are optimistic about their prognosis, but who have some inadequate beliefs about LBP. Again, most of these predictors have been established as predictor of chronic LBP (somatization<sup>22,24</sup>; fear avoidance<sup>23,24</sup>; susceptibility for chronic LBP<sup>26,27</sup>).

The finding that MIS seemed to be more suitable for patients with a higher level of education was, in retrospect, not very surprising as in a short time period (consultation with the GP of 20 minutes) several psychosocial obstacles to recovery were addressed and discussed.

**Table 2. Potential Predictors of a Clinically Important Improvement at 6 Weeks Among Patients in the UC Group (n = 163) and MIS Group (n = 142)**

	UC OR [95% CI]	P	MIS OR [95% CI]	P
<b>Socio-demographic variables</b>				
Age		0.73		0.70
30–50 vs. 18–30 yr	0.96 [0.40; 2.27]		0.75 [0.27; 2.07]	
50–65 vs. 18–30 yr	0.73 [0.28; 1.91]		0.62 [0.20; 1.90]	
Gender		0.98		0.88
Male vs. female	0.99 [0.54; 1.83]		1.05 [0.54; 2.03]	
Educational level		0.08*		0.14*
Secondary vs. primary	2.26 [1.12; 4.56]		1.49 [0.70; 3.15]	
College/university vs. primary	1.75 [0.66; 4.63]		2.68 [1.02; 7.08]	
Paid job		1.0		0.60
Yes vs. no	1.00 [0.37; 2.70]		1.29 [0.50; 3.29]	
Health insurance		0.87		0.15*
Private vs. public	1.06 [0.55; 2.04]		1.70 [0.82; 3.51]	
<b>Characteristics of LBP</b>				
Pain intensity during the day		0.72		0.28
4–6 vs. 0–3	1.12 [0.54; 2.36]		1.93 [0.84; 4.42]	
7–10 vs. 0–3	0.81 [0.33; 1.98]		1.77 [0.69; 4.54]	
Radiation of pain		0.16*		0.65
Yes vs. no	0.64 [0.34; 1.19]		0.85 [0.43; 1.68]	
Radiation of pain below knee		0.40		0.07*
Yes vs. no	1.47 [0.60; 3.62]		0.36 [0.12; 1.07]	
Duration current LBP episode (days)†		0.00*		0.12*
per day			0.97 [0.95; 0.99]	
8–30 vs. 0–7	0.59 [0.29; 1.20]			
31–90 vs. 0–7	0.12 [0.04; 0.42]			
Frequency of LBP episodes last year		0.00*		0.01*
≥3 vs. 1 or 2	0.27 [0.14; 0.53]		0.40 [0.20; 0.80]	
Other pain sites than LBP		0.31		0.17*
Yes vs. no	0.72 [0.38; 1.37]		0.61 [0.30; 1.22]	
Severity of the main complaint		0.64		0.04*
4–6 vs. 0–3	2.08 [0.45; 9.61]			
7–10 vs. 0–3/0–6	1.88 [0.43; 8.29]		2.07 [1.02; 4.22]	
<b>Psychosocial factors</b>				
Fear avoidance (FABQ; 0–24)†		0.71		0.10*
per point			1.05 [0.99; 1.12]	
>15 vs. ≤15 (median split)	0.89 [0.48; 1.64]			
Catastrophizing (CSQ; 0–36)†		0.01*		0.82
per point	0.93 [0.89; 0.98]			
>11 vs. ≤11 (median split)			0.92 [0.48; 1.80]	
Distress (4DSQ; 0–32)		0.15*		0.70
>10 vs. ≤10	0.62 [0.33; 1.18]		0.87 [0.43; 1.77]	
Somatization (4DSQ; 0–32)†		0.03*		0.01*
per point	0.92 [0.86; 0.99]			
>10 vs. ≤10			0.28 [0.12; 0.67]	
Influence on health (1–4)†		0.09*		0.06*
per point	1.48 [0.94; 2.35]			
Much influence (4), reasonable (3) vs. no influence (1), hardly any (2)			1.98 [0.96; 4.07]	
Perceived general health (SF-36; 1–5)		0.00*		0.78
per point	2.06 [1.31; 3.24]		1.06 [0.70; 1.60]	
Responses of important others (MPI; 0–6)				
Punishing responses		0.58		0.31
>0 vs. 0 (median split)	0.83 [0.44; 1.58]		1.42 [0.72; 2.80]	
Solicitous responses†		0.74		0.01*
per point			1.42 [1.08; 1.87]	
>3.3 vs. ≤3.3 (median split)	1.08 [0.70; 1.66]			
Distracting responses†		0.23		0.61
per point	0.89 [0.73; 1.08]			
>2.3 vs. ≤2.3 (median split)			1.19 [0.61; 2.33]	
<b>Estimations by GP or patient</b>				
GP estimation of the risk the patient will develop LBP†		0.03*		0.12*
per point	0.78 [0.62; 0.97]			
3–10 vs. 0–2 (median split)			0.58 [0.29; 1.14]	
Effectiveness of MIS, estimated by the GP for each patient (0–10)				0.42
6–10 vs. 0–5 (median split)			0.75 [0.37; 1.50]	
Patient estimation of the risk to develop chronic LBP		0.01*		0.00*
per point	0.85 [0.75; 0.95]		0.83 [0.73; 0.93]	

LBP = low back pain; UC = usual care; MIS = minimal intervention strategy; OR = odds ratio; CI = confidence interval; FABQ = Fear Avoidance and Beliefs Questionnaire (the higher the score, the more fear avoidance); CSQ = Coping Strategies Questionnaire (the higher the score, the more pain catastrophizing); 4DSQ = 4 Dimensional Symptom Questionnaire (the higher the score, the more distress/somatization); SF-36 = Short Form Health Survey (the higher the score, the better health); MPI = Multidimensional Pain Inventory (the higher the score, the more punishing, solicitous, distracting responses); GP = general practitioner.

\* $P < 0.20$ . These variables were selected for the multivariable analysis.

†This potential predictor showed a linear relation with outcome in the one group and a nonlinear in the other.



**Table 3. Multivariable Model With Predictors of a Clinically Important Improvement at 6 Weeks After Stepwise Backward Selection**

	OR [95% CI]	P
<b>UC</b>		
Duration current LBP episode (days)		0.00
8–30 vs. 0–7	0.59 [0.27; 1.29]	
31–90 vs. 0–7	0.10 [0.03; 0.38]	
Frequency of LBP episodes last year		0.00
≥3 vs. 1 or 2	0.30 [0.15; 0.63]	
Catastrophizing thoughts (CSQ; 0–36)	0.94 [0.89; 0.99]	0.03
per point		
Perceived general health (SF-36; 1–5)	1.52 [0.93; 2.46]	0.09
per point		
<b>MIS</b>		
Somatization (4DSQ; 0–32) >10 vs. ≤10	0.24 [0.08; 0.70]	0.01
Responses by important others (MPI; 0–6); solicitous responses per point	1.55 [1.12; 2.15]	0.01
Susceptibility to develop chronic LBP, estimated by the patient (0–10) per point	0.85 [0.74; 0.97]	0.02
Duration current LBP episode (days) per day	0.98 [0.95; 1.00]	0.06
Fear avoidance beliefs (FABQ; 0–24) per point	1.07 [0.99; 1.16]	0.07
Educational level		0.08
Secondary vs. primary	1.37 [0.55; 3.40]	
College/university vs. primary	3.78 [1.18; 12.1]	

OR = odds ratio; CI = confidence interval; UC = usual care; MIS = minimal intervention strategy; LBP = low back pain; CSQ = Coping Strategies Questionnaire (the higher the score, the more pain catastrophizing); SF-36 = Short Form Health Survey (the higher the score, the better health); FABQ = Fear Avoidance and Beliefs Questionnaire (the higher the score, the more fear avoidance); 4DSQ = 4 Dimensional Symptom Questionnaire (the higher the score, the more somatization); MPI = Multidimensional Pain Inventory (the higher the score, the more punishing, solicitous, distracting responses).

Also, the finding that the odds of clinically important improvement was much higher for patients who were not somatizing compared with somatizing patients was not unexpected as a minimal intervention aimed at psychosocial issues may not be acceptable for patients who strongly attribute unexplained physical symptoms to somatic disease. For these patients, a more extensive intervention by the GP, such as the application of reattribution techniques, is possibly more suitable.<sup>28</sup>

The positive associations with a favorable outcome of having more fear avoidance beliefs (which will be discussed below) and (over)solicitousness by an important other were more surprising. Main and Parker, however, offer an explanation.<sup>29</sup> They argue that one of the perspectives (over)solicitousness can be considered, is “enhanced well-being.” If increased attention by important others makes a patient feel much better, (over)solicitousness can be seen as an interactive pattern that meets the emotional needs of the parties concerned. For these patients, the MIS approach may resemble the solicitous responses of their partner and may in this way lead to a favorable outcome.

#### **Catastrophizing, Fear Avoidance, and Distress**

According to cognitive-behavioral models of pain, the interpretation of pain as threatening (pain catastrophiz-

ing) may lead to pain-related fear.<sup>30</sup> This fear leads to muscular reactivity, hypervigilance, and/or avoidance behavior, which subsequently lead(s) to increased levels of disability, disuse, and depression.<sup>31</sup> Our theory on the working mechanisms of MIS was that identification and discussion of pain catastrophizing, fear avoidance beliefs, and distress would lead to modification of these factors, eventually leading to a better functioning.

While our previous paper showed no differences between UC and MIS in pain catastrophizing at baseline or 6 weeks,<sup>32</sup> pain catastrophizing appeared to be a predictor of an unfavorable outcome in the UC group, but not in the MIS group. One may hypothesize that pain catastrophizing is an important predictor of short-term outcome (as shown in the UC group), but when addressed during treatment (in the MIS group) the negative effects of pain catastrophizing may be reduced. However, if this is true, why was MIS then not more effective than UC in our subgroup analyses among patients with elevated baseline scores on pain catastrophizing?<sup>8</sup> This question, for now, remains unanswered.

In the MIS group, fear avoidance beliefs were, against our expectation, positively associated with improvement, whereas no association was found in the UC group. Our previous study showed no differences between both groups in fear avoidance at baseline or 6 weeks.<sup>32</sup> One may hypothesize that fear avoidance beliefs were not a predictor of short-term outcome (as demonstrated in the UC group), but that when these beliefs were addressed by the GP (in the MIS group) the following may apply: the more fear avoidance beliefs the patient has, the more possibilities there are for intervening on these inadequate beliefs and thus the more appropriate the MIS approach is. George *et al* found that, compared with standard care, participants with higher fear-avoidance beliefs receiving a fear-avoidance treatment had less disability after 4 weeks and 6 months, while participants with lower fear-avoidance beliefs receiving the fear-avoidance treatment appeared to have more disability.<sup>33</sup> The authors propose that educational material aimed at fear-avoidance distracts the patient with lower fear-avoidance beliefs rather than that it reinforces the desired message.<sup>33</sup> This, however, does not explain why MIS was not more effective than UC in our subgroup analyses among patients with elevated baseline scores on fear avoidance.<sup>8</sup>

Distress did not show an association with improvement in any group. While two reviews<sup>23,24</sup> found strong evidence for the role of distress/depressive mood in the transition from acute to chronic LBP, another review<sup>22</sup> presents evidence against this. This latter review proposes that the state of distress varies with the LBP course. In the acute phase (<3 weeks), the worries and fear may only illustrate that the patient mobilizes his resources to deal with the pain, and distress may therefore not be a predictor of poor outcome. But after a few weeks, when the pain does not improve, depressive symptoms may develop, negatively influencing recovery of symptoms.

## ■ Conclusion

Two remarks should be made regarding the interpretation of the data. First, in view of the high proportion of patients reporting recovery after 6 weeks (50%), the presented ORs seriously overestimate the underlying relative risks (RR): for example, an OR = 0.3 represents a RR of approximately 0.45; an OR = 3 a RR of approximately 1.55.<sup>34</sup> Second, although our approach yielded two different models with AUCs implying fair discrimination, the two models cannot yet be interpreted or used as a tool for allocating UC or MIS to individual patients. Our study should be regarded as an exploratory study.

The results of our randomized clinical trial<sup>8</sup> provided no evidence that (Dutch) general practitioners should adopt MIS in patients with (sub)acute LBP. In view of future research, we would like to hypothesize that, for at least two groups of patients, UC may be less favorable. The first group includes patients who fit the MIS profile outlined in this paper. For this group, MIS may be more effective than UC. To explore this hypothesis, we need a randomized controlled trial in which patients will participate who fit at least some elements of the MIS profile. The second group of patients for whom UC may be less favorable includes patients possessing characteristics opposite to that of the UC profile outlined in this paper. These more complex cases of LBP may need additional treatment other than UC or MIS.

Finally, also in other so-called “negative trials” characteristics of patients showing a favorable outcome may differ substantially between intervention groups. Considering the many negative trials in LBP research, reanalyzing these data and subsequent validation of the profiles may contribute to the important question: what intervention works for whom?

## ■ Key Points

- While a randomized controlled trial showed no differences in average effect, the present study showed that the characteristics of patients showing a favorable outcome did differ across the two intervention groups.
- Although the discriminative ability of both prognostic models was adequate, the two models cannot yet be interpreted or used as tools for allocating treatments to patients.
- The approach used in this paper may eventually contribute to the important question: what intervention works for whom?

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